MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL CONSUMER P
FORT WASHINC

McN Individual Safety Report

Mfr report #

3117578-0-00-0

Approved by FDA on 11/16/93

Page ___ of ___

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 37 yrs Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death 3/23/94 (mo/day/yr)
- ( ) life-threatening
- ( ) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: 3/23/94 (mo/day/yr)

4. Date of this report: 08/11/98 (mo/day/yr)

5. Describe event or problem

Consumer's written report of DEATH allegedly associated with the use of Extra Strength TYLENOL® acetaminophen Gelcaps in her daughter. According to consumer, daughter experienced flu symptoms (FLU SYNDROME) and an unspecified time later died from liver failure (HEPATIC FAILURE). No further information was provided.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Gelcaps

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown

#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 LFA819

#2

7. Exp. date (if known)

#1 5/31/95

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- ( ) literature
- (x) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 08/11/98

5.
(A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH
FLU SYNDROME
LIVER FAILURE

9. Mfr. report number

1018511A

E. Initial reporter

1. Name, address & phone #

AUG 17 1998

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.